



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/874,460	06/16/97	WEI	Y 1488.042001
			EXAMINER

HM11/0428
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DRAWER'S C	PAPER NUMBER
ATT UNIT	

1646

DATE MAILED: 04/28/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on the election of 2-18-98

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-20 is/are pending in the application.
Of the above, claim(s) 15-16, 18-20 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1, 8-14 is/are rejected.
☒ Claim(s) 2-7, 17 is/are objected to.
☒ Claim(s) 1-20 where are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-848.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 2-7-10-16-17

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-848

☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

Part III: Detailed Office Action

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1646, Group 1640, Technology Center 1600.

5 **2. Restriction Requirement:**

Applicant's election with traverse of Group I, claims 1-14 and 17 in Paper No. 6 of 2-18-98 is acknowledged. The traversal is on the ground(s) that restriction is only proper where the examine can show serious burden, which the examiner has not done. This is not found persuasive because most contrary to applicants position, the search and examination of the 5 groups would pose a very serious burden on the examiner. Further contrary to applicant's position, the previous written restriction did in fact set forth reasons to establish the serious burden.

The requirement is still deemed proper and is therefore made FINAL.

10 **3. Formal Matters:**

The specification objected to for failing to recite the most recent address for the ATCC (see page 3, and 6-7 of the specification). Correction is requested. Furthermore, since some of the claims rely on the use of this novel deposit, the specification needs to comply with all of the provisions of the Rule for deposited material as set out in MPEP Chapter 2400. A copy of the contract is also requested.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title or the like is suggested for the elected inventive concept: DNA ENCODING CHEMOKINE BETA-15"

4. Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, and 8-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims fail to find support by way of a written description in the specification for a reproducible method of how the percent identity is determined. At pages 8, 16-19, and 28-29 of the specification, applicants set forth different percentage that the inventive concept is to encompass and at page 28 merely define what they intend by "similarity". Although the specification states methods which can be used to determine such it is not clear which particular method was used to determine the percent identity upon which the claims rely. Because the sequence identity can be determined by various means and produce different results and different degrees/percents of identity, the skilled artisan would not be able to determine the metes and bounds of the claims for such and the skilled artisan would not know which method was used or which one to use in order to obtain a percent identity consistent with that of the claims. In the absence of such teaching, it would be difficult to determine the point of reference. Also, there are no specific teachings to indicate whether this percent identity is restricted to the protein coding region, or if this is for contiguous regions, or if it takes into account the presence of both intron and exon regions. The specification also fails to set forth the **specific parameters** used in the method, thus, the claims are indefinite as they rely on reference to percent identity.

Claim 8 is also indefinite and confusing because it is not clear what is meant or intended by the statement that the sequence would consist of only A and T residues.

4a. Claims 8-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the full length sequence and certain modified forms, does not reasonably provide enablement for epitope of unspecified characteristic as in claim 8. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification is not commensurate in scope to enable the breadth of each of these

claims, because the description does provide full support for all sequences that constitute nucleic acid sequences that would encode for an epitope-bearing regions. There are no structure/function studies, and the specification at pages 30-34 merely represent the recitation of general procedures for determining epitopes. The claims do not state that the epitope has to be a certain regions and what portion of the encoded amino acid sequence this would be. In the absence of such information, the skilled artisan would be faced with undue experimentation for practicing the full scope of the claims. With regard to claims 8 which refers to hybridizable sequences, the specification is further non-enabling because there are no specific teachings what the sequence that hybridize has to be. Based on the manner in which this claims is written, there is no way to determine if this small sequence will have the desired specificity, because the claims would appear to encompass non-specific sequences that are un-related to that associated with the encoded sequence of the chemokine.

5. *Rejections Over Prior Art:*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims

under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5a. Claims 8-9 are rejected under 35 U.S.C. 102(a) or (b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) Adams et al or Hillier et al.

The prior art disclose a sequence that has a substantial amount of sequence identical to the nucleic acid sequence of the claims (see the sequence alignment). Furthermore, the claims are drafted in such a way that they do not require that the nucleotide sequence has to encode for a particular protein having specified characteristic. The prior art does not teach that the sequence will encoded protein by the same name as recited by the claims, but based on the identical sequence, it would have been expected that the prior art would hybridize to the sequence of the claims. Furthermore, in view of sequence identity, it would be expected that this sequence would encode for an epitope-bearing portion of the encoded protein-thus satisfying the claim limitation. In the absence of anticipation, it would have been obvious to use the prior art sequences to obtain the claimed encoded epitope-bearing regions based on their common properties.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The other art listed on the 892 is cited as of interest to show related art.

7. Claims 2-7 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1 and 10-14 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action.

The cancellation of claims 8-9 would obviate the prior art rejection, and amending the

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claims as in the previous paragraphs that **object** to the claims would place the claims in condition for allowance.

8. Advisory Information:

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to **Garnette D. Draper, Art Unit 1646, whose telephone number is (703) 308-4232**. Examiner Draper can normally be reached Monday through Friday, 9:30 A.M. to 6:00 P.M.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 305-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an informal fax is being transmitted.


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